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PATfix™ - At-line monitoring of impurities and critical quality attributes in biopharmaceutical up- and downstream processes using HPLC fingerprinting

Aleš Štrancar¹, Sebastijan Peljhan¹, Tomas Kostelec¹, Romina Žabar¹, Blaž Goričar¹, Vid Skvarča¹, Vignesh Rajamanickam², Valentin Steinwandter³ and Patrick Sagmeister³

¹BIA Separations, Slovenia

²Vienna University of Technology, Austria

³Exputec GmbH, Austria

Production of high value biological therapeutics usually involves complex manufacturing processes with high process variability. Additionally, development of robust and reliable bioprocesses can be challenging. PAT aims to enhance bioprocess understanding and implies a holistic approach to ensure that quality is built into products by design. Efficient PAT therefore calls for fast and robust analytical techniques which enable to assess high quality information about critical quality attributes and key performance indicators as parallel as possible to the manufacturing process. PATfix™ is unique HPLC system for routine gradient separations that enables every analytical task. Equipped with bio-inert ceramic pump heads is deliberately tailored to meet the demands of analytical applications covering wide range of biomolecules. Highly sensitive and fast multi-wavelength detector enables to detect component peaks even in very fast gradients.

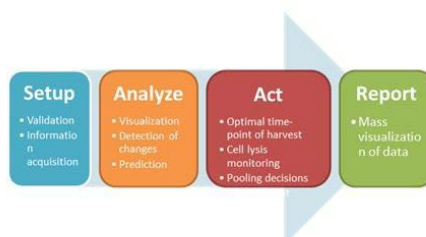


Figure 1: Exputec inCyght® Chromatography Data Science Software offers a user-friendly and powerful toolbox for the analysis of chromatographic data sets.

Biography

Aleš Štrancar is the CBDO of the BIA Separations and one of the main inventors of the CIM Convective Interaction Media®. He is author and co-author of more than 60 scientific papers dealing with separation and purification technologies, a co-author of five granted USA patents and their foreign equivalents in the field of biomolecule separations and purification and a co-author of several book chapters dealing with novel chromatography technologies for biomolecule separation. He co-developed several industrial scale purification processes. He was the President of Technology Council of Ministry of Economy of the Republic of Slovenia and Member of Science and Technology Council of the Republic of Slovenia.

ales.strancar@biaseparations.com

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